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# Can podiatrists impact on self-management for people with type II diabetes?

## Proposal for a randomised controlled trial



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### Background

Type II diabetes has reached epidemic levels in the UK. It is the principle reason for lower limb amputation, renal failure, blindness and a major cause of fatal heart disease.

Effective management of the condition ultimately means good self-management by people living with diabetes on a daily basis. Dietary changes to improve blood sugar (HbA<sub>1c</sub>) control present ongoing challenges for patients and health care professionals.

Podiatrists are one of the most likely professions to have regular consultations with diabetic patients who have developed complications. They are well placed to implement long-term support of patients' self-management.

Embedding a cognitive behavioural model (CBM) into routine diabetic consultations provides a pragmatic solution to improving self-efficacy and making best use of NHS resources (David, 2006; Scottish Government, 2009).

### Methods

This will be a multi-factorial randomised controlled trial (figure 1). Podiatrists, recruited from three diabetic clinics in Scotland, will complete a CBM intervention training programme delivered by a dietician and a psychologist (CPD accredited).

Over a 12 month period, they will implement didactic or CBM interventions with diabetic patients (table 1) to improve self-efficacy and dietary changes.

### Multi-Factorial Randomised Control Trial Design

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graph TD; A[Identify NHS trust/s] --> B[Recruit Podiatry Participants]; A --> C[Recruit Patient Participants]; B --> D[Deliver & evaluate intervention training]; D --> E[Podiatrists implement intervention]; C --> F[Random allocation]; F --> G[Group 1: Dietary Intervention]; F --> H[Group 2: Dietary + CBM intervention]; F --> I[Control group: Usual Care]; E --> G; G --> J[Outcomes monitored]; H --> J; I --> J; J --> K[/Qualitative data/]; J --> L[/Quantitative data/];
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Figure 1: Trial design

### Aims

- to assess the effectiveness of podiatrists implementing CBM with type II diabetic patients
- to promote the use of person-centred collaborative consultations in NHS healthcare
- to improve quality of life for people living with diabetes

Mixed methodologies will be used to evaluate the effectiveness of the intervention in its entirety. The primary biomedical outcome - HbA<sub>1c</sub> - will be monitored as part of usual care.

Diabetes Quality of Life and Diabetes Treatment Satisfaction Questionnaires will be used at baseline and completion points. Process evaluation through interviews and focus groups will provide a picture of how the interventions were used and experienced by both patients and podiatrists

### Statistical analysis

The biomedical data will be analysed with ANOVA tests according to the intention-to-treat principle.

Thematic analysis and coding will be used for qualitative data, and completed before the quantitative data to prevent interpretation bias.

Inclusion	Exclusion
Type II Diabetes	Involved in other clinical trials
Body Mass Index>25	Co-existing systemic diseases that impact on ability to participate
Regular podiatric consultations	Children
Blood glucose levels monitored 2 monthly via HbA <sub>1c</sub> tests	On medication causally linked to weight loss/gain

Table 1: inclusion/exclusion criteria

David, L (2006) *Using CBT in General Practice: The 10 minute Consultation* Scion: Oxfordshire, UK  
Scottish Government (2009) *Long Term Conditions Collaborative: Improving Self Management Support* Scottish Government: Edinburgh  
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